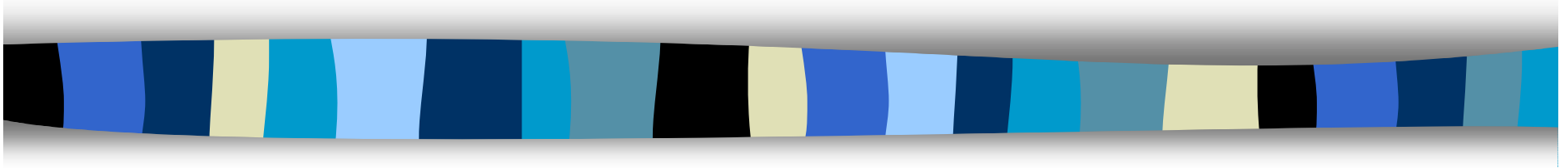


# Rapid Testing in Clinical Practice



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June 10, 2004



# Current Options for HIV Testing

- “Traditional” blood test
- Oral mucosal testing
- Urine test
- Rapid test
- EIA with Western Blot or IFA confirmation



# Rapid Diagnostic HIV Testing

- Results available same day
- Some are easy to perform
- Some can be done on-site
- Patients can complete counseling or other services while test running
- Increase testing options that physicians, clinics, local health departments and other sites can offer



# Potential Advantages for Rapid Testing

- More patients will know HIV status
- More people in care, treatment, and prevention services
- Important to get pregnant women into proper care to reduce risk of vertical transmission
- Important for occupational exposures PEP decision-making



# Public Health Need for HIV Rapid Tests

- CDC estimates 40,000 new infections/year
- Many persons do not return for results
- Need for immediate test results for treatment decisions
  - Perinatal - women in labor
  - Occupational PEP
- Screening high-volume, high-prevalence settings



# Impact of Rapid Test on Return Rate for Results

<u>Site</u>	<u>Prevalence</u>	<u>Return for Results</u>	
		<u>HIV+</u>	<u>HIV-</u>
HIV C/T	1.9%	82.1%	84.3%
STD clinic	1.6%	67.8%	48.1%
Drug Rx	2.9%	73.6%	70.8%
Fam Plan	0.4%	76.9%	63.0%
Other	2.1%	73.2%	64.6%
Rapid Test		97.0%	93.0%

Source: CDC Client Record Database, 1995



## Result Return Rate: Publicly Funded Sites New Jersey 2002

- 66,763 HIV tests performed
- 43,693 (65%) test results received
- 23,070 (35%) test results not received
- 946/1327 (71%) HIV + results received
- 381 HIV + (29%) results not received
- 42,747 (65%) HIV - results received
- 22,689 (35%) HIV - results not received



# Rapid Testing Publicly Funded Sites in NJ 11/1/03 – 4/15/04

- 5 sites
- Total tested 1,013
- Total received results 1,013 (100%)
- Total negative 971 (96%)
- Total positive 42 (4%)
- New positives 27/42 (64%)





# FDA Approved Rapid Tests

- SUDS
- OraQuick
- Reveal
- Unigold
- All need confirmation with Western Blot or IFA
- Rapid testing recommended by CDC



# Rapid Diagnostic HIV Tests: SUDS

- 1st FDA approved rapid test in US
- Needs to be done in a licensed lab
- Proficiency testing
- Centrifuge specimen
- Multiple reagents
- Subtle blue color change
- Problem = false + due to PPV



# PPV: Single Screening Test (SUDS)

## HIV Prevalence

- 10%
- 5%
- 3%
- 1%
- 0.5%
- **0.3%**
- 0.1%

## PPV

- 96%
- 91%
- 86%
- 67%
- 50%
- **38%**
- 18%



# What Does the Table Mean?

- If the HIV prevalence is 0.3%
- The PPV = 38%
- Therefore, only approximately 1/3rd of the time does a positive test represent a person who is actually infected with HIV
- Incorporated in posttest counseling
- Need an FDA approved confirmatory test



# Rapid Tests: OraQuick

- Fingerstick, purple top tube, OMT
- CLIA Waived by FDA 1/03 not OMT
- Not CLIA waived in NJ (lab regs)
  - Need a lab licensed by NJDHSS for diagnostic immunology (HIV testing)
  - Need to comply with CLIA '88 regs
- ? Point of Service Testing



# Requirements for OraQuick Testing

Have an adequate quality assurance program

Assurance that operators will receive and use instructional materials

QA guidelines for OraQuick testing and sample forms:

[www.cdc.gov/hiv/testing.htm](http://www.cdc.gov/hiv/testing.htm)



# The Need for Training

- Blood & body fluid precautions
- Obtaining the specimen (finger stick or blood draw)
- Performing the test
- Providing test results and counseling
- Quality assurance
- OSHA requirements



## Remember the tradeoffs...

- Good News: More HIV-positive people receive their test results.
- Bad News: Some people will receive a false-positive result before confirmatory testing.





**OraQuick: Oral fluid, serum, whole blood**



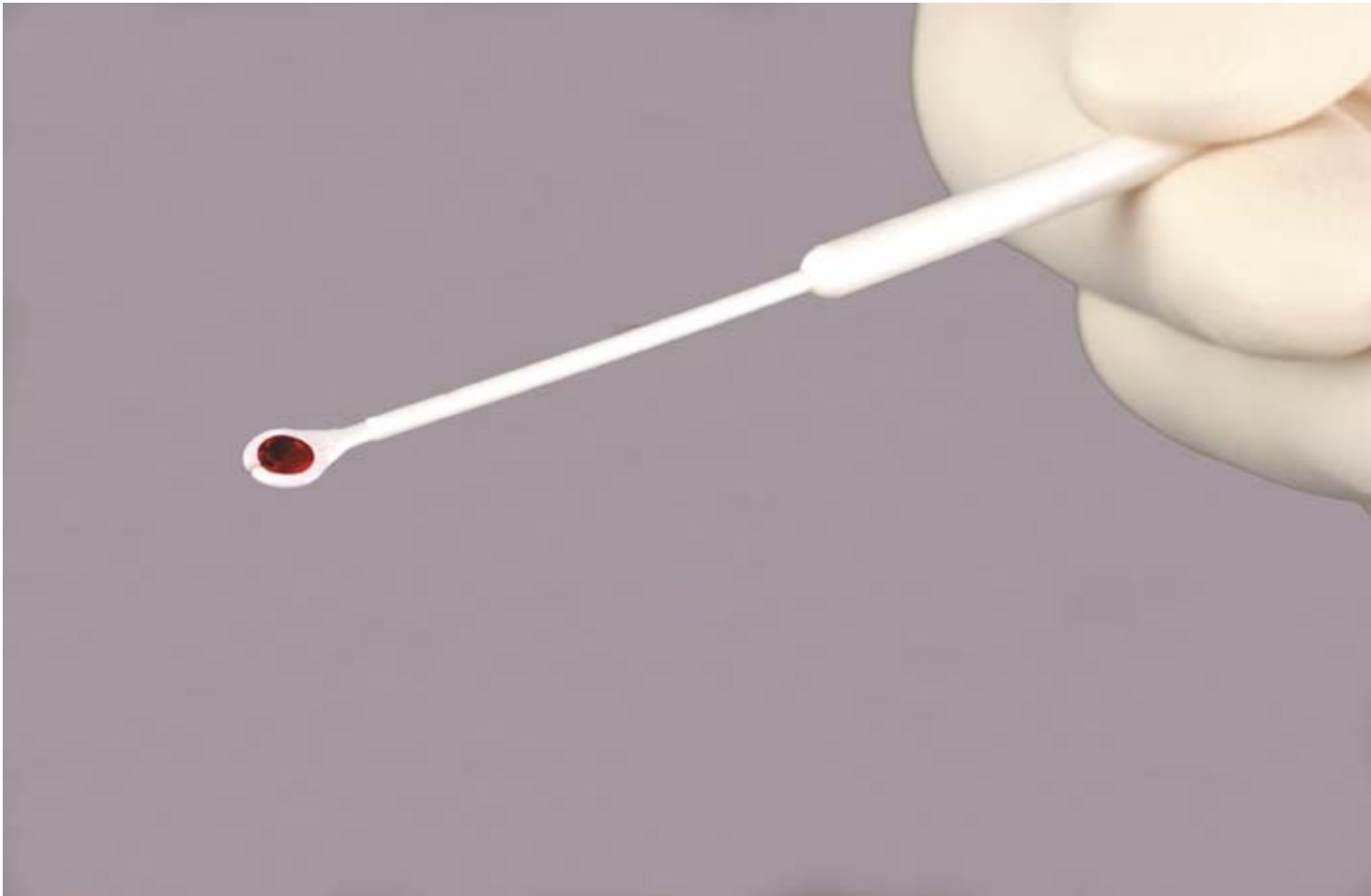
**FDA-approved for use with whole blood; granted CLIA waiver.**



**Obtain finger stick specimen...**



**Or whole blood**



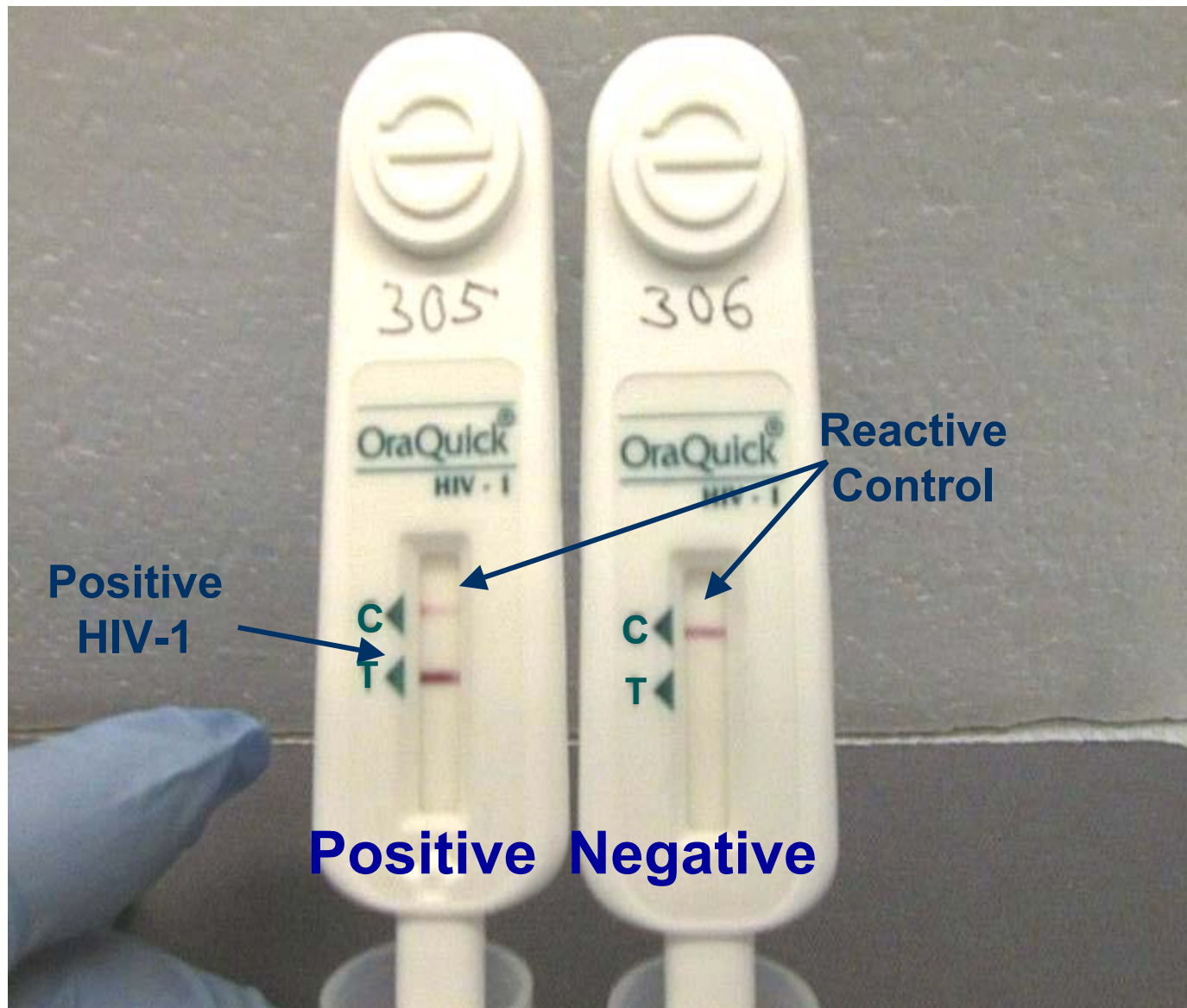
**Loop collects 5 microliters of whole blood**



**Insert loop into vial and stir**



**Insert device; test develops in 20 minutes**



**Read results**



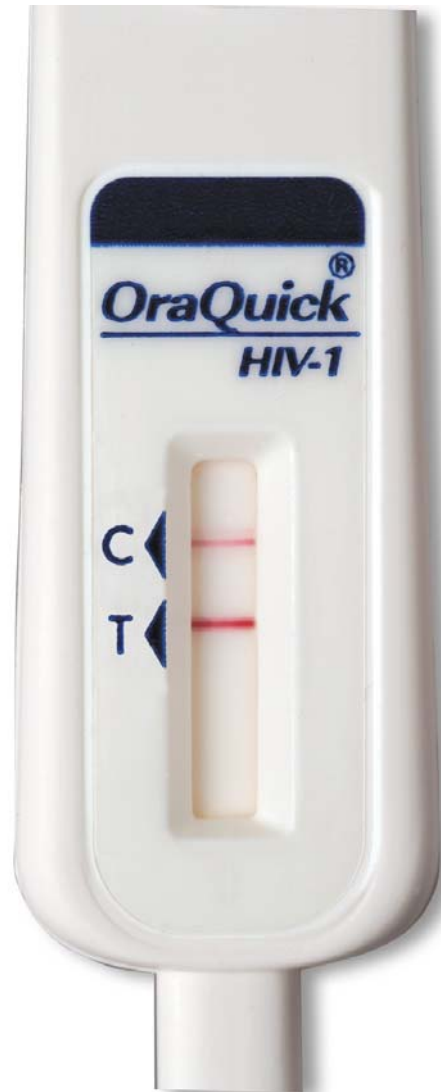


## Example: Three possible OraQuick test results

- Non-reactive
- Reactive
- Invalid



**Non-reactive**



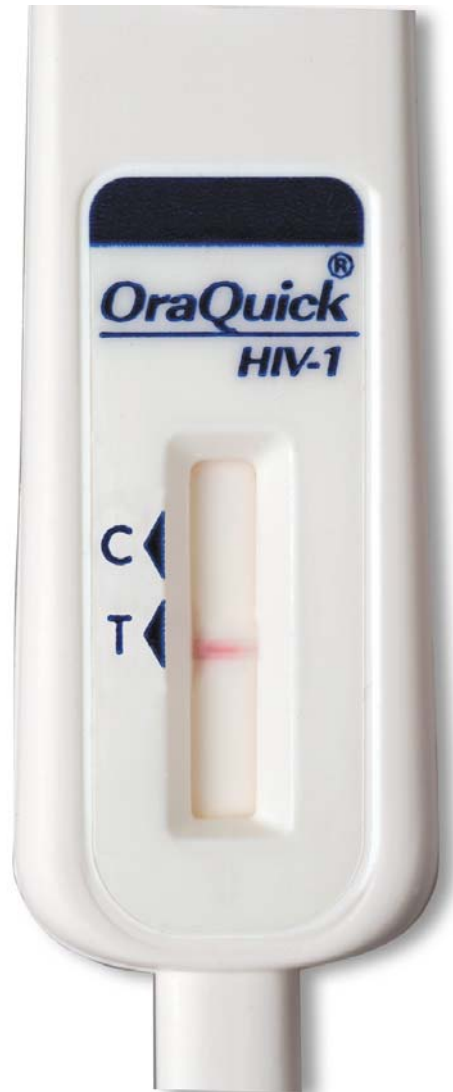
**Reactive**



**Invalid**



**Invalid**



**Invalid**



**Invalid**



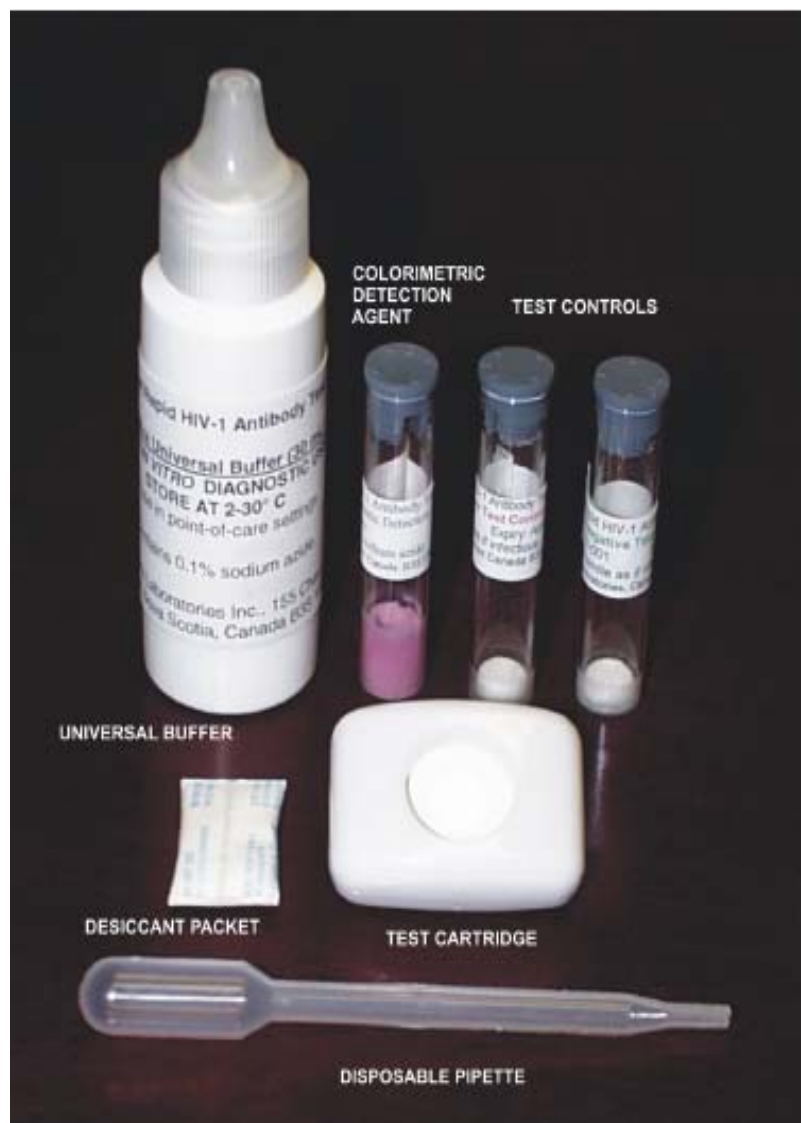
**The challenge:  
Weakly Reactive**





# Rapid Tests: Reveal

- FDA approved 4/17/03
- Not CLIA waived
- Moderate complexity test
- Most be done in licensed lab
- Batched - minimum 8 specimens/batch
- Expensive due to control packaging (3/pack need to use 5/test)



**Reveal HIV-1 Rapid Antibody Test for serum, plasma**  
**CLIA Category - Moderate Complexity**



**Centrifuge to obtain serum or plasma**



**Add 20 drops of buffer to reconstitute conjugate. (Refrigerate to store)**

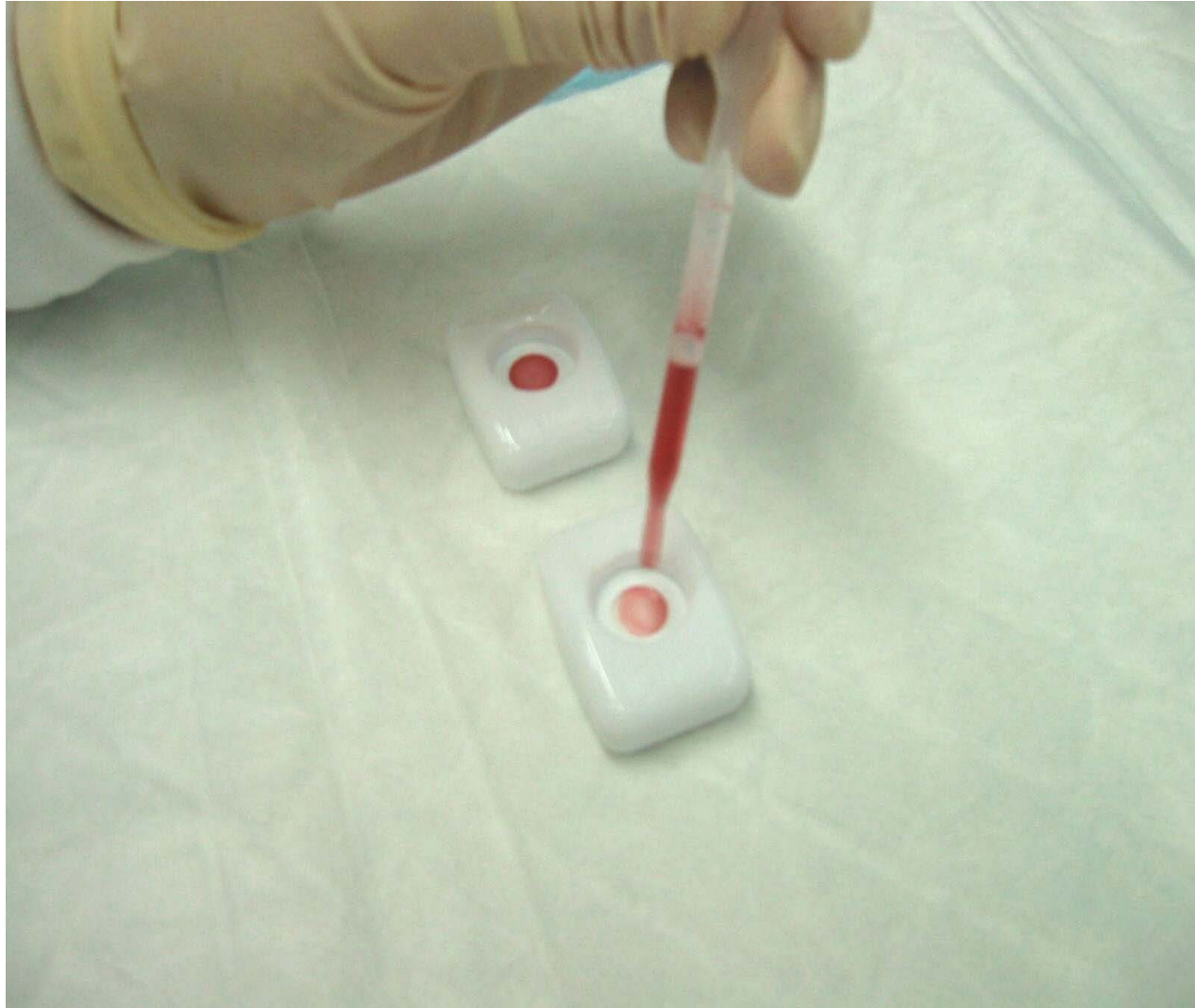


**Add 3 drops buffer to moisten  
membrane**





**Add one drop of serum or plasma,  
followed by 3 drops of buffer.**

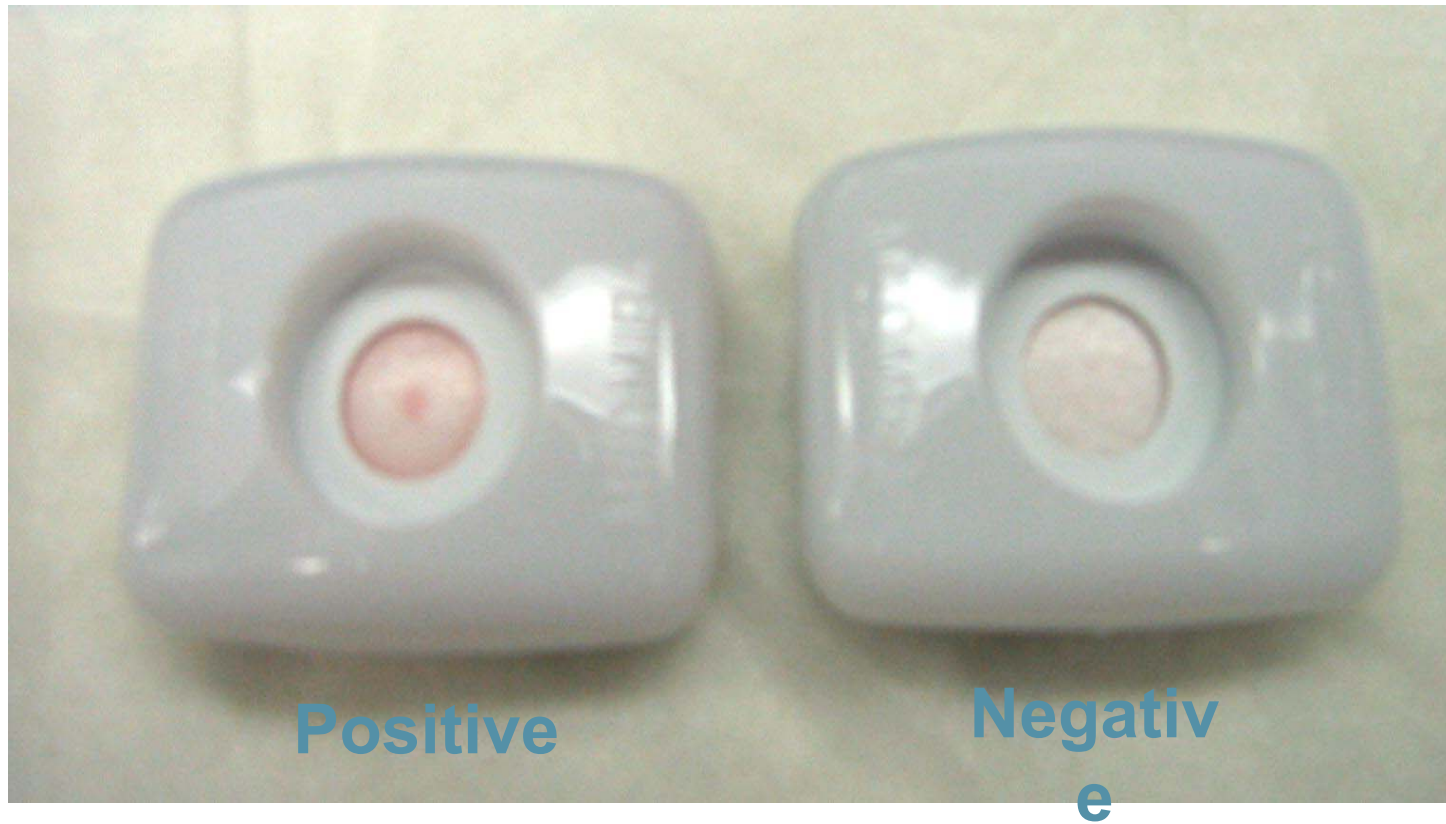


**Add 4 drops of conjugate solution**



**Add 3 drops of buffer to wash**





**Read results immediately**



# Uni-Gold Recombigen

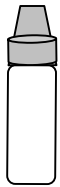
- FDA approved 12/03
- Not CLIA Waived
- Must be done in laboratory
- 10 minute test
- Whole blood, serum, or plasma
- 1 step test

# Uni-Gold™ Recombigen® HIV

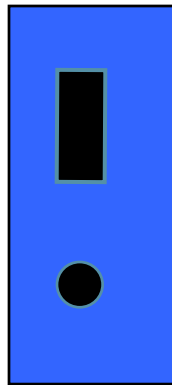


# Uni-Gold™ Recombigen® HIV Assay Procedure

**Step 1:** Removed required number of devices and pipettes.  
(If stored at 2-8°C allow devices to come to room temperature).

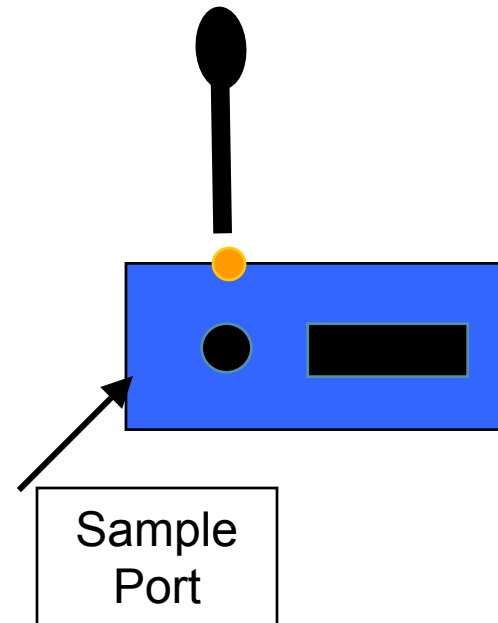


Buffer Pipette



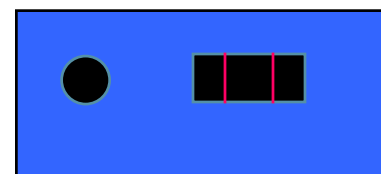
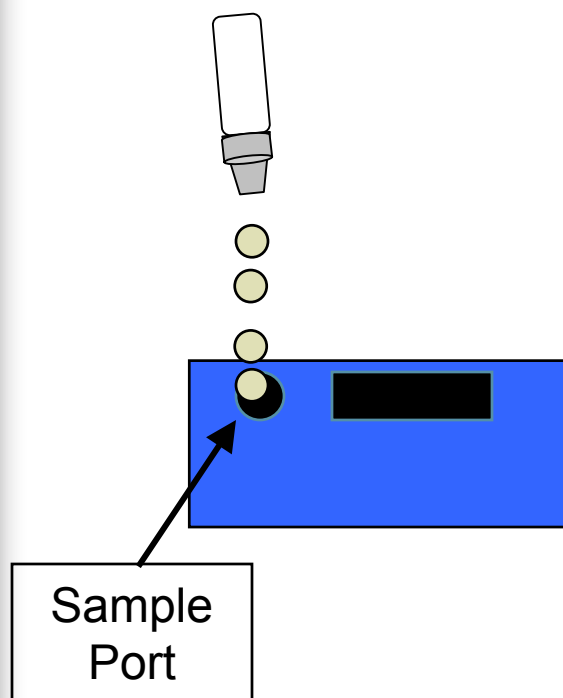
Uni-Gold™ HIV device

**Step 2:** Add 1 drop of sample to the sample port in the device using the pipette supplied



# Uni-Gold™ Recombigen® HIV Assay Procedure

**Step 3:** Add 4 drops of wash buffer **Step 4:** Read the result at 10 minutes.



# How do other Rapid Tests Perform Compared to SUDS?

	False Negative	Sensitivity	False Positive	Specificity
<b>Determine</b>	0/37	100%	2/1649	99.9%
<b>Reveal</b>	5/67	93.1%	16/1581	99.0%
<b>MultiSpot</b>	0/45	100%	0/769	100%
<b>OraQuick</b>	0/73	100%	2/1639	99.9%
<b>OraQuick Oral</b>	0/72	100%	18/1569	98.9%
<b>Unigold</b>	4/45	91.1%	2/915	99.8%
<b>SUDS</b>	1/72	98.6%	6/1641	99.6%
<b>1649 Clients at Testing Site / STD Clinics</b>				



# Current Clinical Response to Rapid Testing Prelim + Results

- Occupational Exposure
- Women in labor with unknown HIV status
- Why? Because tested person benefits
  - PEP reduces risk of occupational transmission
  - Short course therapy reduces risk of mother-to-child HIV transmission



# Pre-Test Counseling for the Rapid Test

- NJDHSS training prepared and available
- Let person know results will be available the same day
- If patient not want same day results have alternative test available
- Consent for testing
- Counseling continues while test running





# Post Test Counseling for Rapid Test: Negative Test

- Same as you currently do for post test counseling of a negative result
- As always emphasize risk reduction plan to prevent transmission
- Note: a negative rapid test is negative and does not need confirmation that it is negative



# Post Test Counseling Rapid Test: Preliminary Positive Result

- Need to return for confirmatory results
- Include phrases such as
  - “a good chance of being infected” or
  - “very likely infected” to communicate probability + positive rapid test result reflects infection with HIV
- HIV prevalence & assessment of each patient’s individual risk should be discussed



# Post Test Counseling Rapid Test: Confirmed Positive Result

- As always emphasize risk reduction plan to prevent transmission to partner(s)
- Try to elicit needle-sharing &/or sexual contacts
- Refer needle-sharing &/or sexual contacts to NAP 877-356-8312
- Refer for treatment, social services etc



## Summary

- On-site, same day service
- Helpful for prevention
- Good for women in labor & occupational
- More people will know their HIV status
- More people will be able to access treatment and other services
- Need licensed lab or affiliation with licensed lab